EXHIBIT 35

Proceedings of the International Consensus Meeting on Periprosthetic Joint Infection

Chairmen:

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Foreword

"The doorstep to the temple of wisdom is a knowledge of our own ignorance."

Benjamin Franklin

The battle against infection is as old as human civilization. During the last few centuries, great scholars such as Louis Pasteur, Ignaz Philipp Semmelweis, Alexander Fleming, and Joseph Lister have transformed the practice of medicine through their extraordinary discoveries. Despite the progress made and strides gained, our mission to prevent infection following surgery remains unaccomplished. It is not an exaggeration to claim that fear of infection lives in the hearts of every surgeon who steps into the operating room daily.

Periprosthetic joint infection (PJI), with all its disastrous implications, continues to pose a challenge to the orthopaedic community. Practicing orthopaedic surgeons have invested great efforts to implement strategies that may minimize surgical site infection (SSI). Although high-level evidence may support some of these practices, many are based on little to no scientific foundation. Thus, there is a remarkable variation in practices across the globe for prevention and management of PJI.

Should one use a laminar flow room for elective arthroplasty? How much and which antibiotic should one add to cement spacers? What metric should one use to decide on the optimal timing of reimplantation? What are the indications and contraindications for irrigation and debridement? How many irrigation and debridement in a joint should be attempted before resection arthroplasty needs to be considered? And what is the best type of skin preparation prior to surgery? These are among the many questions that the orthopaedic community faces on a daily basis. While some aspects of our practice are in dire need of a higher level of evidence to support them, others can hardly be subjected to the scrutiny of a randomized study, and an effort to generate evidence in support of these practices may be laborious and difficult indeed.

The medical community comprehends the importance of high-level evidence and engages in the generation of such whenever possible. The community also recognizes that some aspects of medicine will never lend themselves to the generation of high-level evidence nor should one attempt to do so. It is with the recognition of the latter that The International Consensus Meeting on Periprosthetic Joint Infection was organized. Delegates from various disciplines including orthopaedic surgery, infectious disease, musculoskeletal pathology, microbiology, anesthesiology, dermatology, nuclear medicine, rheumatology, musculoskeletal radiology, veterinary surgery, pharmacy, and numerous scientists with interest in orthopaedic infections came together to evaluate the available evidence, when present, or reach consensus regarding current practices for management of SSI/PJI. The process of generating the consensus has spanned 10 months. Every stone has been turned in search of evidence for these questions,

with over 3,500 related publications evaluated. The evidence, when available, has been assessed. Otherwise the cumulative wisdom of 400 delegates from 51 countries and over 100 societies has been amassed to reach consensus about practices that lack higher level of evidence. The members of the Musculoskeletal Infection Society (MSIS) and the European Bone and Joint Infection Society (EBJIS), the two societies whose mission is to improve care of patients with musculoskeletal infection, have contributed to this initiative immensely.
The delegates have been engaged every step of the way by communicating through a "social" website generated for this purpose, with over 25,000 communications exchanged. The consensus document has been developed using the Delphi method under the leadership of Dr. Cats-Baril, a world-renowned expert in consensus development. The design of the consensus process was to include as many stakeholders as possible, allow participation in multiple forums, and providing a comprehensive review of the literature. The topics that were covered included the following: mitigation and education on comorbidities associated with increased SSI/PJI, perioperative skin preparation, perioperative antibiotics, operative environment, blood conservation, prosthesis selection, diagnosis of PJI, wound management, spacers, irrigation and debridement, antibiotic treatment and timing of reimplantation, one-stage versus two-stage exchange arthroplasty, management of fungal or atypical PJI, oral antibiotic therapy, and prevention of late PJI. Every consensus statement has undergone extreme scrutiny, especially by those with expertise in a specific area, to ensure that implementation of these practices will indeed lead to improvement of patient care.

After synthesizing the literature and assembling a preliminary draft of the consensus statement, over 300 delegates attended the face-to-face meeting in Philadelphia and were involved in active discussions and voting on the questions/consensus statements. The delegates first met on July 31 in smaller workgroups to discuss and resolve any discrepancies and finalize their statements. Then, the delegates met in the general assembly for further discussion of questions and consensus statements. After revising the consensus statements, the finalized consensus statement was assembled and the document was forwarded to the Audience Response System that evening for voting to begin the next day. On August 1, 2013 the delegates came into the general assembly and voted on the 207 questions/consensus statements that were being presented. The voting process was conducted using electronic keypads, where one could agree with the consensus statement, disagree with the consensus statement, or abstain from voting. The strength of the consensus was judged by the following scale: 1) Simple Majority: No Consensus (50.1-59% agreement), 2) Majority: Weak Consensus (60-65% agreement), 3) Super Majority: Strong Consensus (66-99% agreement) and 4) Unanimous: 100% agreement. Of the 207 questions, there was unanimous vote for one question (controlling OR traffic), 202 questions received super majority (strong consensus), two questions had weak consensus, and only two questions did not achieve any consensus.

The document presented here is the result of innumerable hours of work by the liaisons, leaders and delegates dedicated to this historic initiative. The information conveyed in this document is based on evidence, whenever present, or is the result of cumulative wisdom of over 400 of world's experts in musculoskeletal infection from 58 countries. We are certain that the "best practice guide" set forth by this initiative will serve many of our patients for years to come. It is essential to state that the information contained in this document is merely a guide to practicing physicians who treat patients with musculoskeletal infection and should not be considered as a "standard of care". Clinicians should exercise their wisdom and clinical acumen in making decisions related to each individual patient. In some circumstances this may require implementation of care that differs from what is stated in this document.

On with our fight against infection.

Thorsten Gehrke MD

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Acknowledgements:

A project of this magnitude is not possible without the assistance and leadership of many. We would like to thank Mitchell Maltenfort PhD, manager of Biostatistics and Bioethics at the Rothman Institute, who has been a critical player in orchestrating literature review, document development, and the numerous edits that have followed. Tiffany Morrison MS, and her team should single-handedly be given most of the credit for their leadership in organization of the meeting, which was no small task. Tiffany and her team had worked long hours in the months preceding the meeting to ensure every detail was covered and should be credited for the success of this meeting.

Special thanks to Katherine Huff BA, from the Rothman Institute, for her invaluable editorial skills and detail-oriented mind that could see the trees in the massive forest and ensured the accuracy of every statement made in this document.

We need to thank Greg Chang and his team from ForMD that provided the “social” platform for communication. Numerous interactions and invaluable discussions that took place between delegates would not have been possible without the ForMD. The team should be congratulated for their hard work and extremely responsive attitude that allowed efficient and timely communication between members of the consensus.

Dr. Sandra Berríos-Torres, from the Centers for Disease Control and Prevention, needs a special mention as she has provided us with her expertise and leadership throughout the consensus process and specifically worked with liaisons of some workgroups. She was also kind to attend the meeting in person. As a technical expert representing a United States federal agency, Dr. Berríos-Torres did not vote on any of the consensus statements. While we are unable to include her as a delegate in the document, her contributions to this initiative are greatly appreciated.

With Immense Gratitude to our Sponsors

A meeting of this magnitude could not take place without the generous support of industry partners whose mission parallels ours in providing better care for patients. We are indebted to every one of our industry partners for their financial support and more critically for their scholarly input throughout the process. We appreciate their input during the literature review and refinement of questions and their agreement not to be part of the “voting” delegates.

Platinum Sponsor:

Question 1: Do numbers of bacteria arriving in the surgical wound correlate directly with probability of SSI?

Consensus: We recognize that the probability of surgical site infection correlates directly with the quantity of bacteria that reach the wound. Accordingly we support strategies to lower particulate and bacterial counts at surgical wounds.

Delegate Vote: Agree: 97%, Disagree: 2%, Abstain: 1% (Strong Consensus)

Justification: Postoperative surgical site infections are believed to occur via bacterial inoculation at the time of surgery or as a result of bacterial contamination of the wound via open pathways to the deep tissue layers.[1-3] The probability of surgical site infection is reflected by interaction of parameters that can be categorized into three major groups.[2] The first group consists of factors related to the ability of bacteria to cause infection and include initial inoculation load and genetically determined virulence factors that are required for adherence, reproduction, toxin production and bypassing host defense mechanisms. The second group involves those factors related to the defense capacity of the host including local and systemic defense mechanisms. The last group are environmental determinants of exposure such as size, time and location of the surgical wound that can provide an opportunity for the bacteria to enter the surgical wound, overcome the local defense system, sustain their presence, replicate and initiate local as well as systemic inflammatory reactions of the host.

The use of iodine impregnated skin incise drapes shows decreased skin bacterial counts but no correlation has been established with SSI. However, no recommendations regarding the use of skin barriers can be made (See Workgroup 4 Question 27).

Question 2: Do numbers of bacteria in the operating room environment correlate directly with the probability of surgical site infection?

Consensus: We recognize that airborne particulate bacteria are a major source of contamination in the operating room environment and that bacteria shed by personnel are the

predominant source of these particles. The focus of our recommendations is to reduce the volume of bacteria in the operating room with particular attention to airborne particles.

Delegate Vote: Agree: 93%, Disagree: 5%, Abstain: 2% (Strong Consensus)

Justification: Air is a potential source of contamination in the operating room.[2, 4] Studies have demonstrated that the number of airborne bacteria around the wound is correlated to the incidence of PJI.[1] It has been suggested that if it was possible to measure accurately the number of bacteria present in the wound it should constitute the most precise predictor of subsequent infection.[5] Bacteria can be considered as part of the total mass of particulates in the air. Some studies have suggested that the airborne particulate count should be considered as potential surrogate for airborne microbial density.[6] Others have found correlation between the number of particulates larger than 10 micrometers with the density of viable bacteria at the site of surgery (measured by colony forming units).[7] It has been suggested that monitoring particulate count be used as a real-time proxy for increased risk of wound contamination or infection.[7] Persons in the operating room are major source of bacterial load and shed bacterial particulates. These particulates circulate through the operating room via air currents. Movements of objects (personnel and/or operating room equipment including opening and closing doors) can generate significant marked air currents and increase the probability of bacteria being deposited in the surgical site.[3, 8]

Question 3: Should the operating room (OR) in which an elective arthroplasty is performed be fitted with laminar air flow (LAF)?

Consensus: We believe that arthroplasty surgery may be performed in operating theaters without laminar flow. Laminar flow rooms and other strategies that may reduce particulates in operating rooms would be expected to reduce particulate load. Studies have not shown lower SSI in laminar flow rooms and some cases, are associated with increased rates of SSI. These are complex technologies that must function in strict adherence to maintenance protocols. We do recommend further investigation in this field.

Delegate Vote: Agree: 85%, Disagree: 7%, Abstain: 8% (Strong Consensus)